510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k042193

B. Purpose for Submission:
New Device

C. Analyte:
Glycated Serum Proteins (Fructosamine)

D. Type of Test:
Quantitative

E. Applicant:
Diazyme Laboratories

F. Proprietary and Established Names:
Diazyme Glycated Serum Protein Enzymatic Assay Kit
Diazyme Glycated Serum Controls

G. Regulatory Information:

1. Regulation section:
   21 CFR 864.7470 Glycosylated Hemoglobin Assay
   21 CFR 862.1660 Quality Controls

2. Classification:
   Class II - 21 CFR 864.7470 Glycosylated Hemoglobin Assay
   Class I (reserved) - 21 CFR 862.1660 Quality Control

3. Product Code:
   Diazyme Glycated Serum Protein Enzymatic Assay and Calibrators- LCP
   Diazyme Glycated Serum Controls- JJX

4. Panel:
   Chemistry (75)

H. Intended Use:

1. Intended use(s):
   Diazyme Glycated Serum Protein Enzymatic Assay Kit in conjunction with Diazyme Glycated Serum Protein single calibrator, are intended for the quantitative determination of glycated serum proteins (fructosamine) in

serum. The measurement of glycated serum proteins (fructosamine) is useful for monitoring diabetic patients.
Diazyme Glycated Serum Protein Enzymatic Assay Kit contains a single standard. The standard is used in the calculation of glycated serum protein concentrations in unknown serum samples.
Diazyme Glycated Serum Protein Enzymatic Assay has controls for normal glycated serum protein level and abnormal glycated serum protein level. The controls are used as reference samples for checking the functionality of the Diazyme Glycated Serum Protein Enzymatic Assay.

2. Indication(s) for use:
   Diazyme Glycated Serum Protein Enzymatic Assay Kit in conjunction with Diazyme Glycated Serum Protein single calibrator, are intended for the quantitative determination of glycated serum proteins (fructosamine) in serum. The measurement of glycated serum proteins (fructosamine) is useful for monitoring diabetic patients.
   Diazyme Glycated Serum Protein Enzymatic Assay Kit contains a single standard. The standard is used in the calculation of glycated serum protein concentrations in unknown serum samples.
   Diazyme Glycated Serum Protein Enzymatic Assay has controls for normal glycated serum protein level and abnormal glycated serum protein level. The controls are used as reference samples for checking the functionality of the Diazyme Glycated Serum Protein Enzymatic Assay.

3. Special condition for use statement(s):
   For Prescription Use Only

4. Special instrument Requirements:
   This assay can be performed manually or in an automated chemistry analyzer capable of maintaining 37 ºC and reading absorbance at 550 nm.

I. Device Description:

The Diazyme Glycated Serum Protein (Dia-GSP) Enzymatic Assay consists of Proteinase K reagent 1 (R1) and Fructosaminase reagent 2 (R2). R1 digests Glycated Serum Proteins (GSP) into glycated protein fragment (GPF). Reagent 2 catalyzes the oxidation of GPF into fragments and hydrogen peroxide (H_2O_2). The H_2O_2 released is measured by a colorimetric Trinder end-point reaction. The amount of color developed is measured at 550 nm and is proportional to the concentration of GSP in the sample.
The Diazyme Glycated Serum Protein (Dia-GSP) Enzymatic Assay includes the GSP Calibrator. The GSP Calibrator consists of one level (470 μmol/L) and is supplied in lyophilized. The concentrations of fructosyl propylamine of the calibrators were confirmed by the Randox Fructosamine Assay.
The Diazyme Glycated Serum Protein Controls (GSP Controls) are sold separately and consist of 2 levels (250 μmol/L and 647 μmol/L) and are supplied lyophilized.

The concentrations of fructosyl propylamine of the controls were confirmed by the Randox Fructosamine Assay.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Randox Laboratories Limited Fructoasamine

2. Predicate K number(s):
   k023763

3. Comparison with predicate:

Diazyme Glycated Serum Protein Enzymatic Assay

Similarities		
Item	**Device**	**Predicate**
Intended Use	For the quantitative in vitro determination of glycated protein in human serum. The measurement of glycated serum proteins (fructosamine) is useful for monitoring diabetic patients.	For the quantitative in vitro determination of glycated protein in human serum or plasma.
Sample	Serum	Serum, EDTA or Plasma
Principle	Glycated Serum Protein (GSP) concentration is determined through a series of enzymatic reactions and the oxidative degradation of glycated serum fragments to form hydrogen peroxide. The hydrogen peroxide is released and measured colorimetrically and the absorbance at 550 nm is proportional to the concentration of GSP.	Glycated Protein fragments are oxidized by ketoamine oxidase to form hydrogen peroxide. The hydrogen peroxide is measured colorimetrically and is proportional to the concentration of glycated protein in a sample.
Differences		
Item	**Device**	**Predicate**
Assay Range	21 μmol/L to 1354 μmol/L	11 μmol/L to 1734 mmol/L

Diazyme Glycated Serum Controls

Similarities		
Item	**Device**	**Predicate**
Intended Use	Diazyme Glycated Serum Controls is a bi-level control. The controls are used as reference samples for checking the functionality of the Diazyme Glycated Serum Protein Enzymatic Assay.	Randox Fructoasmine Control is bi-level control. The controls are used as reference samples for checking the functionality of the Randox Laboratories Limited Fructosamine Assay.

K. Standard/Guidance Document Referenced (if applicable):
None Referenced

L. Test Principle:
Glycated Serum Protein (GSP) concentration is determined through a series of enzymatic reactions and the oxidative degradation of glycated protein fragments to release hydrogen peroxide. The hydrogen peroxide released is measured by a colorimetric Trinder end-point reaction. The absorbance at 550 nm is proportional to the concentration of GSP.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The Diazyme GSP Enzymatic Assay was run on two specimens of approximately 280 μmol/L and 586 μmol/L, in duplicates for a total of twenty replicates. Specimen 1 obtained a mean of 290 μmol/L with a CV of 2.87% and specimen 2 obtained a mean of 608 μmol/L with a CV of 2.84%.

The Diazyme GSP Controls were tested for reproducibility at two laboratories (on the Hitachi 717 and Randox Daytona) on low and high control serum samples. Site one tested two controls (244 μmol/L and 611 μmol/L glycated serum proteins) in duplicates and obtained an average of 246 μmol/L and 615 μmol/L glycated serum proteins. Site two tested two controls (235 μmol/L and 560 μmol/L glycated serum proteins) in duplicates and obtained an average of 233 μmol/L and 557 μmol/L.

b. Linearity/assay reportable range:

A linearity study was conducted on the Hitachi 717 in duplicates on eight dilutions of glycated serum proteins purchased from Sigma-Aldrich and yielded an equation of $Y=0.9557x + 5.3377$ with a R^2 of 0.9986.

The assay has a linear range of 21 to 1354 μmol/L.

c. *Traceability (controls, calibrators, or method):*
The Diazyme GSP Controls are sold separately from the assay and the Calibrators are included with the assay. The Diazyme GSP Controls and Calibrators are gravimetrically prepared from commercially available reagents. The concentrations of fructosyl propylamine were confirmed by the Randox Fructosamine Assay. Two lots of the Diazyme GSP Enzymatic Assay kits were used in a real-time and an accelerated stability studies. The results of the stability studies supported a claim for reconstituted reagents at 2-8 °C of 28 days and for the lyophilized form at 2-8 °C of 12 months. The Diazyme GSP Calibrators and controls were both studied in real time at 4 °C and the results supported a stability of 4 weeks when reconstituted. The Diazyme GSP calibrators and control in the lyophilized form were evaluated in an accelerated study and the results supported a 12 weeks stability claim at 25 °C.

d. *Detection limit:*
See Linearity section above.

e. *Analytical specificity:*
Interference was tested on substances normally present in the serum with Diazyme GSP Enzymatic Assay by spiking 160 μmol/L glycated protein serum samples. The study found less than 10% deviation when tested with the following substance levels: 2 mM Uric Acid, 200 mg/dl Haemoglobin, 133 mM Glucose, 2000 mg/dl Triglycerides, 0.230 mM Ascorbic Acid and 20 mg//dl Bilirubin.

f. *Assay cut-off:*
Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*
Sixty-five real patient serum samples were tested with both the Diazyme GSP Enzymatic Assay and the Randox Fructosamine Assay. On the Hitachi 717. The Diazyme GSP calibrator and controls were gravimetrically prepared with commercially available reagents and was verified by the Randox Fructosamine Assay. The equation in the correlation study was $Y=0.9981x + 4.984$ with a R^2 of 0.9789.

b. *Matrix comparison:*
Not applicable

3. Clinical studies:
    a. *Clinical sensitivity:*
    Not applicable

    b. *Clinical specificity:*
    Not applicable

    c. *Other clinical supportive data (when a and b are not applicable):*
    Not applicable

4. Clinical cut-off:
    Not applicable

5. Expected values/Reference range:
    A normal glycated serum proteins in adults (20 to 60 years) range from 100-285 μmol/L as obtained from the literature was provided.

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.